

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

BRAINTREE LABORATORIES, INC.,)

Plaintiff,)

v.)

CYPRESS PHARMACEUTICAL, INC.,)

Defendant.)

Civil Action No. 12-cv-6851-AJN
ECF Case

**DEFENDANT CYPRESS PHARMACEUTICAL, INC.'S REPLY TO PLAINTIFF
BRAINTREE LABORATORIES, INC.'S OPPOSITION TO MOTION FOR SUMMARY
JUDGMENT OF NONINFRINGEMENT**

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I. INTRODUCTION

Plaintiff Braintree Laboratories, Inc. (“Braintree”) attempts to complicate the issues before this Court by responding to a brief Cypress did not file. Braintree incorrectly suggests that in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 11-cv-01341 (D.N.J.) (“the *Novel Case*”), United States District Judge Peter Sheridan addressed the very same arguments made in Cypress’ Motion for Summary Judgment of Noninfringement, going so far as to “respond” to several arguments from the *Novel Case* that Cypress never made. Braintree also filed voluminous documentation regarding issues, such as validity, that are not currently before this Court and addresses claim elements not at issue in Cypress’ Motion. Passing these irrelevancies, Braintree’s response to Cypress’ actual arguments rely on an incorrect interpretation of the phrase “about 100 ml to about 500 ml” and a misapplication of the law, and fails to explain how Cypress’ ANDA Product, which requires administration of 946 ml of solution during the administration period, could infringe the claims of United States Patent No. 6,946,149 (“the ’149 patent”), all of which require a composition volume of “about 100 ml to about 500 ml.” For the reasons set forth in Cypress’ opening brief and the additional reasons set forth below, Cypress’ Motion for Summary Judgment of Noninfringement should be granted.

II. ARGUMENT

Cypress’ motion for summary judgment boils down to one simple question: if Cypress’ ANDA is approved by the FDA, will Cypress sell a product having a volume of “about 100 ml to about 500 ml?” The answer is no. The product Cypress will sell pursuant to its ANDA, is a ***two-bottle product*** that ***requires*** a patient to ingest a total of ***946 ml*** of aqueous solution. Based on the written public record of the patent prosecution (upon which the public is entitled to rely), throughout the prosecution Braintree and the United States Patent and Trademark Office

(“USPTO”) both used the “about 100 ml to about 500 ml” volume limitation to refer to the *total* amount of solution ingested by a patient, even when the product is administered according to a split-dose regimen. This is dispositive of the infringement issue. As set forth below, the claim language, specification, and prosecution history of the ’149 patent, the proposed labeling for Cypress’ ANDA Product, and the controlling case law all demonstrate that a *single bottle* of Cypress’ ANDA Product cannot be the basis for a finding of infringement.

A. Braintree’s Litigation-Inspired Claim Interpretation is Contrary to the Plain Meaning of the Claim Language and the Intrinsic Evidence, Both of Which Require a Total Ingested Volume of “About 100 ml to About 500 ml”

Braintree’s primary response to Cypress’ motion is to attempt to create a claim construction dispute over the dispositive “about 100 ml to about 500 ml” limitation by improperly tying the volume limitation to the independent “inducing purgation” limitation, and by suggesting that Cypress seeks to import a “cleansing” limitation into the claims, or to require that “purgation” mean “cleansing.” Cypress did not make these arguments. Rather, Cypress *agrees* with Braintree’s statement that the phrase “about 100 ml to about 500 ml” is “an unambiguous reference to volume.” *See* Opp. at 11.¹ This phrase should be accorded its plain meaning, which requires that the total administered volume of the claimed composition is “about 100 ml to about 500 ml.” *See* MSJ at 14-15. Braintree’s proposed construction, which ties the volume limitation to the separate limitation “for inducing purgation,” is incorrect.

Cypress does *not* argue that the 100 to 500 ml composition of the claims must achieve colon cleansing, but rather discusses the prosecution history and the specification as evidence that the claimed volume limitation refers to the *total ingested volume during the treatment period* (regardless of the ultimate purpose for which the composition is administered). As

¹ Citations to “MF” herein refer to Cypress’ Rule 56.1 Statement of Material Facts, including Braintree’s Counterstatement to those facts. *See* Dkt. 52. Citations to “MSJ” refer to Cypress’ Opening Brief. Dkt. 43. Citations to “Opp.” refer to Braintree’s Opposition Brief. Dkt. 48.

explained below, this is how a person of skill in the art would understand the claims based on their plain language, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*).

First, the plain language of the claim reveals that the phrase “for inducing purgation” is independent and does not redefine the meaning of “about 100 ml to about 500 ml.”² Braintree asks this Court to re-write claims 15 and 18 to require “a composition of about 100 ml to about 500 ml ‘for inducing purgation.’” *See, e.g.,* Opp. at 8. Braintree reorders the phrases to make it appear that the composition need only contain 100 ml to 500 ml of solution that functions to induce purgation, allowing for additional volume that induces “additional purgation.” *See* Opp. at 20. This is contrary to the claim language, which recites “a composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml.” Claims 15 and 18 thus *separately* require that 1) the composition functions to “induce purgation” and 2) the total administered volume of the composition is about 100 to 500 ml.³

Second, the specification makes clear that the “about 100 ml to about 500 ml” limitation refers to the **total** volume of solution ingested by a patient during the treatment period. *See* MSJ at 3-8. The specification - which Braintree has asked this Court to disregard as “irrelevant,” MF ¶¶19-22, and “attorney argument,” Opp. at 11 - “is always highly relevant to the claim

² The introductory phrase “[a] composition for inducing purgation of the colon of a patient” in composition claims 15 and 18 is known in patent law as a “preamble.” *See Catalina Mktg. Int’l. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). Such “preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure.” *Id.* While Judge Sheridan construed “purgation,” his construction in no way suggests that the preamble phrase requiring a certain use for the invention alters the meaning of the volume limitation. Indeed, Judge Sheridan’s claim construction order *never addressed* the 100 ml to 500 ml volume limitation. *See* Dkt. 51-6 at 11.

³ Braintree argues that Cypress’ plain-language interpretation of the claims “ignores” or render meaningless the “inducing purgation” limitation. Opp. at 10, 14. Not so. Cypress has stipulated, for purposes of this motion, that that its product cleanses the colon by “inducing purgation.” Moreover, this does not resolve the question of infringement because regardless of whether the Cypress product “induces purgation,” it does not meet the independent limitation, present in every claim of the reexamined ’149 Patent, requiring the composition to have a volume of “about 100 ml to about 500 ml.” *See* MSJ at 13.

construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315 (quotation omitted). Here, *every single example* disclosed in the ’149 patent was administered in a split-dose regimen like that required by the proposed label for Cypress’ ANDA Product. ’149 patent, 5:32-6:3 (“One half of each experimental solution was ingested by the subjects on two occasions, at 7 p.m. on day 1 and at 5 a.m. on day 2.”); MF ¶12. The specification states that the “volume” of these experimental solutions was “330 ml.” ’149 patent, 5:64-65; MF ¶¶20-22. Thus, the specification describes the “volume” of a composition administered in two doses of 165 ml each, given 10 hours apart, as “330 ml” - the *total volume ingested by the patient*.⁴ ’149 patent, 5:57-6:3. Tellingly, Dr. Cleveland, one of the ’149 patent’s inventors, agrees that the patent specification recites the administration 10 hours apart of two 165 ml doses, for a 330 ml “total volume” chosen to correspond to “the volume of the Fleet’s Phospho-soda” comparator product. Dkt. 50, ¶10.

Third, the prosecution history also teaches that the proper construction of the term “about 100 ml to about 500 ml” refers to the total volume of solution ingested. Braintree consistently distinguished the prior art during prosecution on the basis of the *total volume ingested by the patient*, making no reference to the volume of a “single administration” nor to any minimum amount required to “induce purgation.” See MSJ 5-7; MF ¶¶23-31. An important function of the patent prosecution process is to put the public on notice as to the scope of a patentee’s claims. *Digital Biometrics v. Identix, Inc.*, 149 F.3d 1335, 1347-48 (Fed. Cir. 1998). As a result,

⁴ Braintree accuses Cypress of attempting to “distract” the Court by noting that the volume of SUPREP is nearly three times that of the experimental solutions. Opp. at 13 n.13. Cypress points out this difference in volume because Judge Sheridan was skeptical that the claims of the ’149 patent would not cover SUPREP. See Dkt. 46-15 at 4 n.2. The fact that the inventors developed the higher-volume SUPREP product *after* filing their patent application, see Dkt. 50 ¶¶10-11 (Cleveland Declaration), and the fact that the original claims were later narrowed during reexamination, see MF ¶¶25-26, 34, 39, help explain why Braintree’s patent does not cover its own product.

Cypress is permitted to, and, in fact, is expected to, rely on the written record and the representations Braintree made during prosecution, to determine the proper claim scope. *Id.*

Moreover, Braintree represented to the USPTO that SUPREP - which Braintree admits is identical in volume and dosing regimen to Cypress' proposed generic product - is "0.94L" in volume. *See* MSJ at 8; Dkt. 46-13 at 11; MF ¶¶4-5, 39. This admission was made *in a context directly relevant to Cypress' motion*: Braintree was explaining to the USPTO why SUPREP allegedly met the volume limitation of the original claims of the '149 patent. Braintree offers no substantive reason why this admission should not be binding upon it, but, rather, attempts to downplay its significance by stating that it was a "mistake." *See* Opp. at 14 n.15. This purported excuse does nothing to erase the fact that Braintree has consistently represented to the USPTO that *both bottles* of SUPREP are considered in determining whether the volume limitation is met. Even in the Supplemental Request for Patent Term Extension, Braintree asserts that the volume of SUPREP meets the amended volume claim limitation based on the *combined undiluted volume of both bottles*. Dkt. 46-14 at 12 ("The approved SUPREP Bowel Prep Kit comprises from about 100 ml to about 500 ml volume of solution. Specifically, the product contains 2 x 6 ounce solutions (*i.e.*, approximately $2 \times 0.177 \text{ L} = .354 \text{ L}$ of solution) . . ."). In litigation, Braintree argues the claims mean one thing, but in prosecution, it has consistently represented that they mean another. The public has the right to rely on the representations Braintree made during prosecution, *Digital Biometrics*, 149 F.3d at 1347, and this Court should reject Braintree's litigation-inspired arguments.

Braintree's heavy emphasis on Dr. Puera's opinion regarding the meaning of claim terms, *see* Opp. at 11-12, is contrary to *en banc* Federal Circuit precedent. The Federal Circuit has held that extrinsic evidence, such as expert opinion, is "less reliable than the patent and its

prosecution history in determining how to read claim terms.” *Phillips*, 415 F.3d at 1318. Thus, “a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.” *Id.* (internal quotation omitted). While district courts are given “discretion to admit and use such evidence,” expert opinion is, contrary to Braintree’s assertions, by no means necessary to ascertain claim meaning. *Id.* at 1319. Dr. Puera’s declaration is particularly irrelevant to understanding the meaning of the “about 100 ml to about 500 ml” claim term because he offers only unexplained (that is, conclusory) statements of his “opinion” as to how a person skilled in the art would allegedly understand the claims or the prosecution history. Dkt. 49 ¶¶61-65; *see Phillips*, 415 F.3d at 1318 (“conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court”).

B. Cypress’ ANDA Product Requires a Total Ingested Volume of 946 ml

1. The Dispositive Facts are Undisputed

Braintree does not dispute that the Cypress ANDA Product, administered according to its proposed label, **requires** the patient to consume two 16 ounce containers (*i.e.*, **946 ml**) of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution. MF ¶14. Nor does Braintree dispute that Cypress’ proposed labeling does not include **any** indication that would involve administration of only a **single bottle** of the Cypress ANDA Product. MF ¶17. Further, Braintree agrees that Cypress’ ANDA Product is a kit containing **two bottles**, both of which must be diluted to 473 ml and consumed by the patient to achieve the sole FDA-approved indication for colon cleansing. *See Opp.* at 18-19; MF ¶¶6-7, 14, 16. These **undisputed** facts are dispositive. Cypress is not seeking approval to sell a product consisting of a single bottle of 473 ml of aqueous solution that would fall within the claims of the ’149 patent, nor does the labeling

for Cypress' ANDA Product induce anyone to take only a single bottle without taking the second bottle. MF ¶¶7-9, 14, 17.

While Braintree accuses Cypress of “mischaracterizing” its own ANDA Product in stating that it will be administered as 946 ml of aqueous solution without emphasizing that this volume of solution is consumed in two administrations separated by 10-12 hours (*see* MSJ at 15; Opp. at 15-16; MF ¶¶12, 14-17), Braintree itself has repeatedly represented to the USPTO that it is the volume of *both* bottles that is relevant to its patent claims. As discussed above, in each of the six examples in the '149 patent, the two doses were administered *10 hours apart*. Moreover, Cypress' initial patent term extension request characterizing the “volume” of SUPREP as “0.94L” (940 ml) is consistent with how the '149 patent itself describes the volume of experimental solutions administered in a similar split-dose regimen. *See* Part II.A., *supra*. The claims of the '149 patent do not include any limitation requiring the composition to be ingested without a time separation, so Braintree's focus on the “*separate* 473 ml administrations” is unsupported. *Cf.* Opp. at 16. Indeed, as Dr. Cleveland explains in his declaration, such a split-dose regimen was contemplated from the beginning of development. Dkt. 50, at ¶8. It is the total administered volume over the treatment period, not the timing of ingestion, which is relevant to the infringement inquiry for claims 15 and 18-20.⁵

2. Braintree Misapprehends Infringement Under § 271(e).

While Braintree is correct that the infringement analysis in a Hatch-Waxman case “is determined by traditional patent infringement analysis,” *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003), Braintree mistakenly concludes that an infringement analysis under § 271(e) can ignore how the product is defined by an ANDA applicant's proposed

⁵ Claim 23 *requires* splitting the total volume into two or more administrations. *See* Part II.C. *infra*. This further supports Cypress' position that all of the asserted claims require the *total volume* ingested by a patient (whether in single or multiple administrations) to be “about 100 ml to about 500 ml.” *See id.*; MSJ at 21.

labeling, *see* Opp. at 17-18. Braintree incorrectly argues that *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569-70 (Fed. Cir. 1997), rejects a “patentee’s argument that § 271(e)(2)(A) infringement action requires a unique infringement analysis focused solely on the ANDA.” Opp. at 17. *Glaxo* actually holds that the infringement inquiry under § 271(e)(2) is “properly grounded in the ANDA application and the extensive materials typically submitted in its support.” *Glaxo*, 110 F.3d at 1569. Because the ANDA defines the drug product that will be sold upon FDA approval, the determination of infringement in an ANDA case is made based on what will be the on-label use of the drug product as a whole once it is approved. *Warner-Lambert Co.*, 316 F.3d at 1364-65; *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1325 (Fed. Cir. 2012); *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1250 (Fed. Cir. 2000).

Here, as Braintree admits, Cypress’ proposed label defines the product as a *two-bottle* kit. MF ¶7. Moreover, it is undisputed that the proposed label *requires* a patient to take *both bottles* of diluted solution over the course of an administration period.⁶ MF ¶14. Thus, the Cypress product requires ingestion of a total volume of 946 ml of aqueous solution and is outside the scope of the ’149 patent claims.

3. Failure to View Cypress’ ANDA Product as a Whole Would Render the “About 100 ml to About 500 ml” Claim Limitation Meaningless

Braintree attempts to distinguish *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377 (Fed. Cir. 2000), by arguing that the presence of a functional limitation *somewhere in the claim* alters the unambiguous requirement that the composition comprise “from about 100 ml to about 500 ml of an aqueous solution.” That attempt fails because, unlike in the *Dow Chem. Co.* case Braintree

⁶ Contrary to Braintree’s curious argument, there is no “bizarre scenario” where the determination of infringement under § 271(e)(2) is inconsistent with the determination under § 271(a), because upon approval, Cypress’ product labeling will carry this same requirement. *Cf.* Opp. at 18 n.19.

cites for support, the claims of the '149 patent do not recite a composition “containing about 100 to about 500 ml of solution for inducing purgation” plus other components for some other purpose. *See* Part II.A., *supra*; *cf. Dow Chem. Co. v. Nova Chems. Corp.*, 629 F. Supp. 2d 397, 408 (D. Del. 2009). Braintree admits its theory would divide Cypress’ ANDA Product into one portion “for inducing purgation” and a second portion for inducing “additional purgation.” *See* Opp. at 20. This illustrates the strain in Braintree’s attempt to carve out a portion of Cypress’ product: unlike in *Dow Chem Co.*, there is no limitation in the claims that provides a basis on which to distinguish one portion of Cypress’ product from another.

Finding infringement based on a single bottle of Cypress’ ANDA Product would render meaningless the “about 100 ml to about 500 ml” limitation expressly recited in the claim and added during reexamination to distinguish the prior art. The Federal Circuit consistently rejects patentees’ attempts to ignore portions of an accused product where doing so would “wipe out [an] express limitation” of the claims. *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1379 (Fed. Cir. 2012); *see also Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1327 (Fed. Cir. 2013). That is just what Braintree is asking this Court to do.

C. Cypress’ Labeling Will Not Induce Infringement of the Method Claims of the ’149 Patent

Braintree attempts to re-write claim 23 to demonstrate infringement. Claim 23 does *not* require that the effective amount⁷ of the composition is administered “*two or more times* within a treatment period.” Opp. at 9. Rather, the claim requires that the effective amount is administered “*in two or more doses* within a treatment period.” ’149 patent, 14:17. This language must be understood in the context of the specification. *Phillips*, 415 F.3d at 1415. In

⁷ Cypress did not stipulate to Judge Sheridan’s construction of “effective amount” cited in Braintree’s Opposition at page 9, and construction of the term is unnecessary to Cypress’ argument. *See* Dkt. 41. Either the “effective amount” of Cypress’ product is 946 ml, or the “effective amount” of Cypress’ product is not divided and “administered in two or more doses within an administration period.”

this context, the language of claim 23 clearly refers to *division of* the effective amount into separate administrations. '149 patent, 5:19-24 (“Optimally, *the effective dose may be divided* and administered, to the patient in two, or more administrations over an appropriate time period.”); *see also id.*, 5:49-60 (explaining that subjects ingested “one half” of each experimental solution at “the first dose” and “one half” at “the second dose”). The conclusory opinion of Braintree’s expert, Dr. Puera, provides no explanation as to why a gastroenterologist would understand the language of claim 23 to refer to administering the “effective amount” twice as opposed to *dividing the effective amount into two administrations* as expressly provided by the specification. *See* Dkt. 49, ¶¶73-77. Moreover, Dr. Puera’s opinion is directly contrary to Dr. Cleveland’s declaration statements regarding the intent to administer the product in a split-dose regimen from its conception. Dkt. 50, ¶8.

Properly interpreted in view of the specification, claim 23 refers to division of the “effective amount” into multiple administrations. For Cypress’ product, this means that the “effective amount” is the total volume delivered over two administrations, *i.e.*, $2 \times 473 \text{ ml} = 946 \text{ ml}$. Thus, the volume of Cypress’ product falls outside the claims of the '149 patent, and does not infringe.⁸

III. CONCLUSION

For the reasons set forth in Cypress’ initial brief and the additional reasons set forth above, Cypress’ motion for summary judgment of noninfringement should be granted.

⁸ Cypress explained in its opening brief why Braintree, as a matter of law, cannot assert infringement under the doctrine of equivalents. *See* MSJ at 18-19. Braintree does not respond to Cypress’ argument, and, instead, attempts to reserve the right to respond at another time. Opp. at 6 n.10. Braintree has waived any such response by failing to offer any evidence (or even arguments) as to why there is infringement under the doctrine of equivalents. *See Dineen v. Stramka*, 228 F. Supp. 2d 447, 454 (S.D.N.Y. 2002). Braintree failed to offer any evidence or argument on this point because, having added the “about 100 ml to about 500 ml” limitation during reexamination to escape the prior art, MF ¶¶25-26, 34, it has no good faith basis to claim that Cypress infringes the asserted claims under the doctrine of equivalents. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739-40 (2002).

Dated: August 13, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on August 13, 2013, a true and correct copy of the foregoing
**DEFENDANT CYPRESS PHARMACEUTICAL, INC.'S REPLY TO PLAINTIFF
BRAINTREE LABORATORIES, INC.'S OPPOSITION TO MOTION FOR SUMMARY
JUDGMENT OF NONINFRINGEMENT** was filed through the Court's Electronic Filing
System (ECF), and was served electronically to the registered participants as identified on the
Notice of Electronic Filing (NEF).

/s/ Erik van Leeuwen
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